



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

0061 TO MAY 30 P100

May 30, 2000

Food and Drug Administration  
Dockets Management Branch (HFA-305)  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

Re: International Conference on Harmonisation; E11: Clinical Investigation of Medicinal Products in the Pediatric Population, Docket Number 00D-1223, 65 Federal Register 19777, April 12, 2000

Dear Sir/Madam:

We are forwarding these written comments on the draft guidance for ICH E11: Clinical Investigation of Medicinal Products in the Pediatric Population to be placed on the docket. These comments were sent to us by our European colleagues.

Sincerely,

Rosemary Roberts, M.D.  
Medical Officer  
Center for Drug Evaluation and Research ODE IV

cc: File

00D-1223

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